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ELECTION UNDER 35 USC §121 Examining Group 1634 Patent Application Docket No. SPO-108 Serial No. 09/508,342

Doran R. Pace, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner :

Bradley L. Sisson

Art Unit

1634

Applicants

Yoshiyuki Sakaki, Hajime Tei

Serial No.

09/508,342

Filed

March 10, 2000

Conf. No.

9898

For

Mammalian Genes Involved in Circadian Periods

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

ELECTION UNDER 35 USC §121

Sir:

As an initial matter, Applicants wish to point out that the "Disposition of Claims" section on the Office Action Summary page of the written Restriction Requirement dated May 12, 2003 in the above-identified patent application does not indicate that claims 5, 7, and 10 are canceled and claims 14-16 as submitted in Applicants' Preliminary Amendment dated March 10, 2000 are pending in the subject application. Accordingly, Applicants wish to clarify that claims 5, 7, and 10 have already been canceled and claims 14-16 are pending, along with claims 1-4, 6, 8, 9, and 11-16, in the subject application.

In response to the written Restriction Requirement in the subject application, Applicants hereby provisionally elect to prosecute the invention of Group I (claims 1-7, 11, 12, and 13), with

traverse. Applicants also hereby provisionally elect the amino acid sequence of SEQ ID NO. 1 as the species.

In the instant Restriction Requirement, the Examiner asserts that the inventions listed as Groups I to II do not relate to a single general inventive concept because they lack the same or corresponding special technical features. Specifically, the Examiner asserts that DNA and proteins are different chemical substances, comprised of different subunits, *i.e.*, nucleotides and amino acids, respectively. Applicant respectfully asserts that there <u>is</u> unity of invention for the claimed subject matter. Because this is a national stage application filed under 35 USC §371, the U.S. Patent Office is supposed to apply unity of invention analysis to the claims. What constitutes unity of invention is set forth in the PCT administrative rules. As set forth in PCT Rule 13.1, there is unity of invention if all of the inventions in an application are so linked as to form a single general inventive concept. PCT Rule 13.2 states that unity of invention exists where there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features." The expression "special technical features" is defined in the rules as those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Applicants respectfully assert that the special technical features that link the claims in the subject application define a contribution which each of the inventions makes over the prior art. Applicants note that during the international phase, the PCT application corresponding to the subject U.S. national application was determined to have <u>unity of invention among all claims</u>. Moreover, Annex B of the Administrative Instruction Under the PCT <u>specifically indicates</u> (see Part 2, Example 17, a copy of which is attached for the Examiner's convenience) that a claim to Protein X and a claim to a DNA sequence encoding Protein X have unity of invention. As noted above, the claims in Group I and Group II are directed to a protein and a nucleic acid encoding that protein, respectively. Thus, Applicants respectfully assert that under the PCT rules, and as is clearly illustrated by the specific examples in the PCT rules, unity of invention exists for all the pending claims of the subject application.

Should the Examiner maintain the restriction between Group I and Group II as set forth in the written Restriction Requirement, Applicants respectfully assert that claims 11-16, directed to a vector (comprising the claimed DNA), a transformant (comprising the claimed DNA), and a method of

producing a protein (comprising use of the claimed transformant), should be included in Group II rather than Group I as indicated in the Restriction Requirement. These claims all involve more directly the <u>claimed DNA</u>, rather than the protein. For example, claim 11 recites a vector "comprising the DNA of claim 8." Thus, claims 8-9 and 11-16 share the technical feature of the claimed DNA. Accordingly, Applicants respectfully request that claims 11-16 be included with Group II in the event that the Examiner maintains lack of unity of invention between Group I and Group II.

In the written Restriction Requirement, the Examiner also states that each amino acid or nucleotide sequence is considered to be a patentably distinct chemical compound and, accordingly, upon the election of either Group I or Group II, applicant is further required to elect a single amino acid or nucleotide residue sequence. Applicants respectfully assert that each amino acid sequence should be considered a species of the protein genus and each nucleotide sequence should be considered a species of the DNA genus. Thus, Applicants respectfully assert that the Examiner's requirement for an election of a specific sequence is properly viewed as an election of a species. As the Examiner is aware, PCT Rule 13.4 states that an application can include "a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention." The subject invention includes only two specific amino acid sequences, i.e., SEQ ID NO. 1 and SEQ ID NO. 2, and only two specific nucleotide sequences, i.e., SEQ ID NO. 3 and SEQ ID NO. 4. Furthermore, the sequences of SEQ ID NO. 1 and SEQ ID NO. 2 are homologous to each other, as are the sequences of SEQ ID NO. 3 and SEQ ID NO. 4. Applicants respectfully assert that the number of sequences presented in dependent claims is a reasonable number of species and it would not be unduly burdensome to examine all of the species in the subject application, and such examination is respectfully requested.

In view of the above, Applicants respectfully request reconsideration and withdrawal or modification of the Restriction Requirement. An indication that there is unity of invention for all the claims is respectfully requested.

Applicants invite the Examiner to call the undersigned if clarification is needed or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

Doran R. Pace Patent Attorney

Registration No. 38,261

Phone No.: 352-375-8100 Fax No.:

352-372-5800

Address: 2421 N.W. 41st Street, Suite A-1

Gainesville, FL 32606-6669

DRP/sl

Attachment: Annex B of the Administrative Instruction Under the PCT

MANUAL OF PATENT EXAMINING PROCEDURE

Claim 3: A display with features A + B with additional feature D.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is features A + B.

Example 13

Claim 1: Filament A for a lamp.

Claim 2: Lamp B having filament A.

Claim 3: Searchlight provided with lamp B having filament A and a swivel arrangement C.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is the filament A.

Example 14

Claim 1: A marking device for marking animals, comprising a disc-shaped element with a stem extending normally therefrom, the tip of which is designed to be driven through the skin of the animal to be marked, and a securing disk element to be fastened to the protruding tip of the stem on the other side of skin.

Claim 2: An apparatus for applying the marking device of claim 1, constructed as a pneumatically actuated gun for driving the stem of the disc-shaped element through the skin, and provided with a supporting surface adapted for taking up a securing disc element, to be placed at the other side of the body portion in question of the animal to be marked.

The special technical feature in claim 1 is the marking device having a disc-shaped element with a stem and a securing disc element to be fastened to the tip of the stem. The corresponding special technical feature in claim 2 is the pneumatically actuated gun for driving the marking device and having a supporting surface for the securing disc element. Unity exists between claims 1 and 2.

Example 15

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

Example 16

Claim 1: An insecticide composition comprising compound A (consisting of a 1, a 2...) and a carrier.

Claim 2: Compound a₁.

All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance. There is nevertheless still unity between the subject matter of claims 1 and 2 provided a 1 has the insecticidal activity which is also the special technical feature for compound A in claim 1.

Example 17

August 2001

Claim 1: Protein X

Claim 2: DNA sequence encoding protein X.

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ADMINISTRATIVE INSTRUCTIONS UNDER THE PCT

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

III. MARKUSH PRACTICE

Example 18— common structure:

Claim 1: A compound of the formula:

$$R^3$$
 R^4
 R^2

wherein R¹ is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R²-R⁴ are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case the indolyl moiety is the significant structural element which is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

Example 19— common structure:

Claim 1: A compound of the formula:

wherein R_1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; Z is selected from the group consisting of oxygen (O), sulfur (S), imino (NH), and methylene (-CH₂-). The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

In this particular case the iminothioether group -N=C-SCH₃ linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present. A six membered heterocyclic ring would not have been of sufficient similarity to allow a Markush grouping exhibiting unity, absent some teaching of equivalence in the prior art.

Example 20— common structure

Claim 1: A compound of the formula: